

King, Valerie A.

From: Zedler, Barbara
Sent: Thursday, October 02, 2003 2:32 PM
To: King, Valerie A.
Cc: Mendes, Paul
Subject: RE: Revised Reporting Dates

This looks good and I like the more logical listing order of the studies. I realize I/we are overdue w/ the SCOR6/02/02 draft CSR comments. I am working on a template ABBREVIATED CSR for this one which will incorporate our (also new) template abbreviated CSR (containing only the min safety and demo data reqd by reg agencies per ICH guidelines) which will be what the JLI03/02 CSR is, PLUS the key outcome/efficacy data in the form of source post-text tables/figures, in their orig SAS format, and dragged from their post-text location to Volume 1 in-text, for knowledge purposes. We will list exactly which data tables/figs we want pulled into Vol 1; NO interpretation / narrative will be expected/desired. It is merely to make key outcome data transparent and easily accessible for any future review of the study.

Barb

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-----Original Message-----

From: King, Valerie A.
Sent: Friday, September 26, 2003 6:20 PM
To: Zedler, Barbara; Mendes, Paul; Sarkar, Mohamadi
Subject: Revised Reporting Dates

All:

In light of some of the recent discussions related to report dates, I thought you might find this updated information of interest. This reflects the information Susan sent to us as this week.

I will be updating the report dates in the MDS t/c minutes as well.

-Valerie